

REMARKS

Interview Request

In order to advance prosecution, an interview with the Examiner and the Examiner's supervisor appears to be necessary. Applicant requests that the Examiner call the undersigned to arrange a personal interview.

Status of the claims

Claims 25, 27, 29, 31, 32, 35, 40, 41, 43, 48 – 51 and 57 – 59 are under examination.

Enablement rejections

Claims 25, 29, 31, 35, 40, 41, 43, 50-51 and 57 - 59 stand rejected under 35U.S.C. §112, first paragraph, for lack of enablement. Claims 27, 32, and 48 - 49 are free of this rejection.

Acknowledging that applicants' specification fully enables

an isolated polypeptide comprising the amino acid sequence SEQ ID NO:2, said polypeptide [expressed as] . . . a recombinant polypeptide, a fusion protein comprising the amino acid sequence SEQ.ID.NO:2 and a pharmaceutically acceptable carrier, [and] an isolated polypeptide consisting of an immunogenic fragment sequence of 15 or 20 amino acids of SEQ.ID.NO:2,¹

the Examiner nonetheless contends that the specification "does not reasonably provide enablement for a polypeptide **comprising** an immunogenic fragment sequence of at least 15 or 20 amino acids of SEQ.ID.NO:2, wherein the immunogenic fragment, when administered to a subject in a suitable composition . . . induces an antibody or T-cell response that recognizes the polypeptide SEQ.ID.NO:2."²

Responding to the evidence proffered in applicant's previous response, filed October 21, 2005, the Examiner states that

The examiner is not stating that synthetic peptides can not be used for raising antibodies etc or for mapping epitopes but fragments as claimed (i.e.,

¹ Office action, p. 2.

² Office action, p. 2-3 (emphasis added).

fragment comprising [] at least 15 or 20 contiguous amino acids of SEQ.ID.NO:2) are not supported by the present specification because the limitation [*sic*, "transitional phrase"] "comprising" leaves [] the claim open for the inclusion of unspecified ingredients even in major amounts and therefore does not exclude additional unrecited elements. . . . Therefore, the claimed immunogenic fragment having 15 or 20 amino acids plus unlimited amino acids result[s] in an unknown peptide without structural and functional properties.³ Therefore, the antibodies raised against broadly claimed fragments have not [been] shown to be [capable of] recognizing either the full-length protein or [as being] reactive to fragments consisting of 15 or 20 amino acid[s]. . . .⁴

If correctly understood, the Examiner's concern would appear to be that fragments of SEQ ID NO:2, which are admitted to be capable of eliciting specific antibodies if alone coupled to a carrier protein, are no longer necessarily immunogenic when presented within the context of a larger protein (*i.e.*, a recombinant protein or fusion that comprises the fragment). Even were the Examiner to provide evidence that this is so, and she has not, Section 112 does not require each and every fragment of SEQ ID NO:2 be able to elicit anti-BASB082 antibodies in every protein context, just as § 112 does not require that every single hybridoma resulting from a splenic fusion produce antibodies of a desired specificity, *In re Wands*. All the statute requires is that the skilled artisan be able, without undue experimentation, to make proteins comprising fragments of SEQ ID NO:2, and from the universe of such proteins identify those that can elicit anti-BASB082 antibodies. This was well within the state of the art in 1999. The Examiner having provided no evidence to the contrary, the rejection is in error and should be withdrawn.

Rejections under 35 U.S.C. §102

Claims 25, 29, 31, 35, 40, 41, 43, 50 - 51, and 57 - 59 are rejected under 35 U.S.C. §102(a) as inherently anticipated by Wedege *et al.*, "Immune Responses against Major Outer Membrane Antigens of *Neisseria meningitidis* in Vaccinees and Controls Who Contracted Meningococcal Disease During The Norwegian Serogroup B Protection Trial," *Infection and*

³ The Examiner's comment that the rejected claims read on "unknown peptide without structural and functional properties", arguably a rejection under § 112, *second* paragraph, is nonetheless wrong: each claimed protein comprises a required structural element, a fragment of 15 or more contiguous amino acids of SEQ ID NO:2, and has a required function, the ability to elicit antibodies that recognize an epitope within SEQ ID NO:2.

⁴ Office Action, pp. 4 - 5.

Immunity, 66(7):3223-3231 (1998) (“Wedge”). Claims 27, 32, 48, and 49 are free of this rejection.

Having correctly concluded that Wedge neither explicitly nor inherently describes isolated recombinant proteins comprising, or consisting of, the entirety of applicant's BASB082 protein (SEQ ID NO:2), or fusions thereof, the examiner nonetheless rejects each of applicants' claims that reads more broadly on isolated recombinant proteins or fusions that comprise immunogenic fragments of SEQ ID NO:2:

Claims 27, 32, 48-49 have not been rejected. However, claims 25, 29, 31, 35, 40, 41, 43, 50-51 and 57-59 have been rejected because of open claim language. Therefore, the disclosed protein comprises fragments of SEQ.ID.NO:2 as claimed fragments do not set forth clear structural boundaries.

Charitably put, these comments fall far short of identifying within the Wedge disclosure⁵ each of the elements and limitations upon which the rejected claims uniquely read.

**TO ANTICIPATE A CLAIM, THE REFERENCE MUST
TEACH EVERY ELEMENT OF THE CLAIM.**

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil. Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). . . . "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

M.P.E.P. § 2131 (8th ed., rev. 2) (heading capitalization and font emphasis in the original). The rejection falls short of this standard, and should be withdrawn.⁶

⁵ Described in detail in applicant's last response.

⁶ As for the examiner's additional comment that applicant's arguments that PorA is not BASB082 . . . are again considered as limitations that are not set forth in the claims,

the contention is manifestly contradicted by applicants' recitation of SEQ ID NO:2, either directly, or by dependency, in each of the rejected claims.

Applicants respectfully submit that the claims are in good and proper form for allowance,
and respectfully request the same.

Respectfully submitted,

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